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510(k) SUMMARY
As required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICES

Bisco Pit and Fissure Sealant is a filled, light-cure, white, resin based sealant designed to seal the pits and fissures of caries susceptible teeth.

This product is fabricated from bis-GMA, urethane, or similar room temperature curing diacrylate monomers that are filled with silanated silica and/or glasses.

DESCRIPTION OF THE APPLICANT DEVICE – PIT & FISSURE SEALANT

Cosmedent PIT & FISSURE SEALANT is a light-cure, moderately filled, resin based dental sealant. The product will cure or harden upon application of visible light at a wavelength of approximately 465 nanometers at an energy of at least 350 milliwatts.

PIT & FISSURE SEALANT is a relatively low viscosity polymerizable resin based on bis-GMA, urethane, or similar room temperature curing diacrylate monomers. The product is intended to be applied to the developmental grooves and fissures of teeth to prevent these areas from being damaged by carious organisms. Poor or negligent oral hygiene is likely to predispose pits and fissures damage by caries since these areas readily collect cariogenic foods

PIT & FISSURE SEALANT is available either as a clear unfilled resin or as a filled resin. The filled resin is white and mimics occlusal tooth color. Although closely matching natural tooth color, the margins of the filled resin are more discernable than the clear resin counterpart.

INTENDED USES OF THE APPLICANT DEVICE

PIT & FISSURE SEALANT is intended to be used to seal the pits and fissures of caries susceptible teeth.

James L. Sandrik

James L. Sandrik, PhD

Cosmedent, Inc.
401 N. Michigan Avenue
Suite 2500
Chicago, Illinois 60611
Submitted: October 6, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

James L. Sandrik, PhD
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K042823
Trade/Device Name: Pit & Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: October 07, 2004
Received: October 12, 2004

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Anthony D. Watson for

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K042523

Device Name: MULTIPLE (**PIT & FISSURE SEALANT**)

Indications For Use:

- Dental pit and fissure sealant

Prescription Use___X____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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